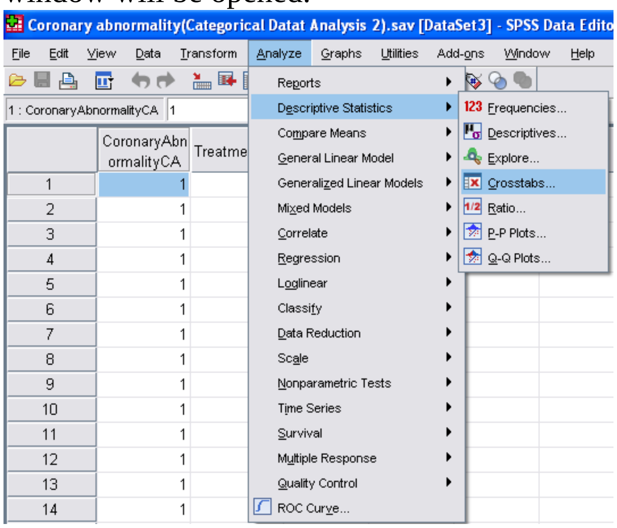
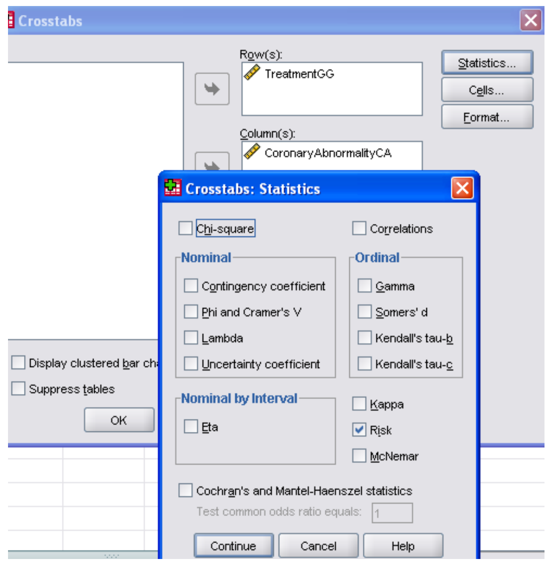
Confidence Interval for Effect Measures

Problem: A clinical trial of gamma globulin in the treatment of children with Kawasaki syndrome randomized approximately half of the patients to receive gamma globulin. The standard treatment for Kawasaki syndrome was a regimen of aspirin: however, about one-quarter of these patients developed coronary abnormalities even under the standard treatment. The outcome of interest was the development o f coronary abnormalities over a 7 week follow up period. The data is available at U:_MT Student File Area\hjkim\STAT380\SPSS tutorial\coronary abnormality.sav. Note that I use 2 instead of 0 for no abnormalities to be consistent with the textbook result.

By clicking on the Analysis and Descriptive statistics and Crosstabs button, the crosstabs window will be opened.





Assign CA as column and GG as row and choose Cell and click Row and Column under Percentage. Click continue. In Cross tab window, choose Statistics. Click Risk as following.

Click continue and OK. We can get the following output.

TreatmentGG * CoronaryAbnormalityCA Crosstabulation

			CoronaryAbnormalityCA		
			abnormalities	no abnormalities	Total
TreatmentGG	Gamma Globulin	Count	5	78	83
		% within TreatmentGG	6.0%	94.0%	100.0%
		% within CoronaryAbnormalityCA	19.2%	55.3%	49.7%
	aspirin	Count	21	63	84
		% within TreatmentGG	25.0%	75.0%	100.0%
		% within CoronaryAbnormalityCA	80.8%	44.7%	50.3%
	Total	Count	26	141	167
		% within TreatmentGG	15.6%	84.4%	100.0%
		% within CoronaryAbnormalityCA	100.0%	100.0%	100.0%

Risk Estimate

	Value	95% Confidence Interval	
		Lower	Upper
Odds Ratio for TreatmentGG (Gamma Globulin / aspirin)	.192	.069	.539
For cohort CoronaryAbnormalityCA = abnormalities	.241	.095	.609
For cohort CoronaryAbnormalityCA = no abnormalities	1.253	1.095	1.434
N of Valid Cases	167		

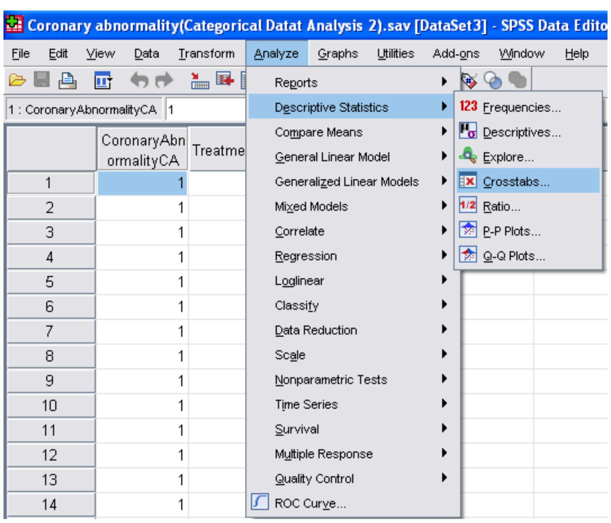
Here, the estimate of risk difference is $\frac{5}{5+78}$ - $\frac{21}{21+63}$ = -0.19, the estimate of relative risk is $\frac{5/(5+78)}{21/(21+63)}$= 0.241, and the estimated odds ratio is $\frac{5/78}{21/63}$ = 0.192.

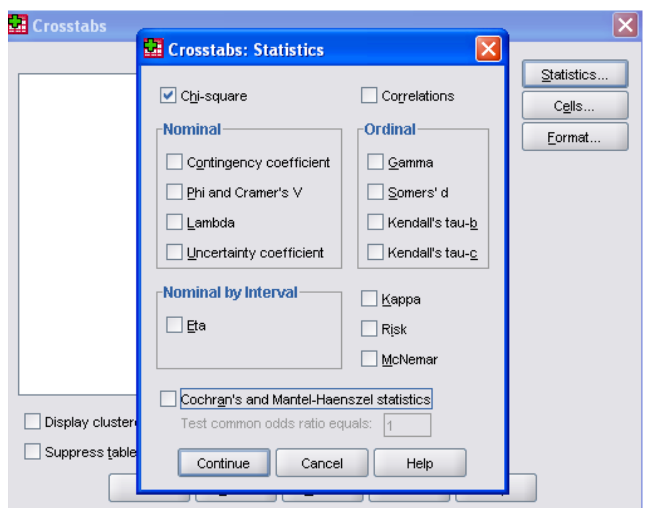
In Risk Estimate table, the first row gives the estimated odds ratio and 95% confidence interval for the odds ratio. The second row gives the estimate of relative risk (abnormality) and the 95% confidence interval for the relative risk. The third row gives the same as the second row but for no abnormality (Note that $\frac{78/(5+78)}{63/(21+63)}$ = 1.253).

<u>Test of Homogeneity and Fisher's exact test</u>

Problem: The treatment of children with Kawasaki syndrome (Continued)

By clicking on the Analysis and Descriptive statistics and Crosstabs button, the crosstabs window will be opened. Assign CA as column and GG as row. Choose Statistics. Click Chi-square as following. You can also get expected values by choosing cells and Expected.





Click continue and OK. We can get the following output.

TreatmentGG * CoronaryAbnormalityCA Crosstabulation

			CoronaryAbnormalityCA		
			abnormalities	no abnormalities	Total
TreatmentGG	Gamma Globulin	Count	5	78	83
		Expected Count	12.9	70.1	83.0
		% within TreatmentGG	6.0%	94.0%	100.0%
		% within CoronaryAbnormalityCA	19.2%	55.3%	49.7%
	aspirin	Count	21	63	84
		Expected Count	13.1	70.9	84.0
		% within TreatmentGG	25.0%	75.0%	100.0%
		% within CoronaryAbnormalityCA	80.8%	44.7%	50.3%
	Total	Count	26	141	167
		Expected Count	26.0	141.0	167.0
		% within TreatmentGG	15.6%	84.4%	100.0%
		% within CoronaryAbnormalityCA	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	**11.436**[a]	**1**	**.001**		
Continuity Correction[b]	10.038	1	.002		
Likelihood Ratio	12.180	1	.000		
Fisher's Exact Test				**.001**	**.001**
Linear-by-Linear Association	11.368	1	.001		
N of Valid Cases	167				

<u>The Chi-square test of Homogeneity</u> can be done by using Pearson Chi-square.

Step 1. H_0: $p_0=p_1$, H_a: $p_0\neq p_1$ (or H_0: $RR=1$, H_a: $RR\neq 1$)

Step 2. χ^2= 11.436

Step 3. The test statistics, 11.436 is larger than the critical $\chi^2_{1,0.05}$=3.84. Thus reject H_0.

Step 4: Reject H_0 since p-value = .001 is less than α=0.05.

Note: To the test be valid each cell has at least 5 expected frequency. Combining the two groups, we see that 26 of the 167 patients developed coronary abnormalities. The estimated risk of coronary abnormalities is 26/167 = .1157. Assuming that the null hypothesis is true, the risk is the same in both treatment groups, and we would expect that 11.57% of the patients develop coronary abnormalities. Among 83 patients in the Gamma globulin, we expect that (.1157)×(83)=9.6031 patient would develop coronary abnormalities.

Note also that this is same as Chi-square independent test for 2 × 2 table.

Fisher's exact test is useful when one or more of the four expected cell frequencies in 2 × 2 table is less than 5. In this example,
6% of the patients treated with Gamma globulin developed coronary abnormalities whereas 25% of patients treated with Aspirin developed abnormalities. The estimated RR is .24. The null hypothesis is H_0: *RR=1*, and H_a: *RR≠1*. We use the two-sided Fisher's Exact test to test the hypothesis. Assuming α=0.05, we reject H_0 since p-value is .001 is less than 0.05. (There is significant evidence that treatment with Gamma globulin developed less coronary abnormalities.)